

REMARKS

Claims 1-8, 10, 12-33, 35-40, 42, and 44-61 are currently pending. No claims have been amended.

1. Rejections under 35 U.S.C. §103(a) over Vega, et al.

Reconsideration is requested of the rejection of claims 1-8, 10, 12-23, 25-33, 35-40, 42, 44-56, and 58-61 under 35 U.S.C. §103(a) as being unpatentable over Vega, et al. (U.S. Patent No. 6,153,209).

Claim 1 is directed to an absorbent product comprising an absorbent substrate and a moisturizing and lubrication composition. The moisturizing and lubricating composition comprises from about 1% (by weight) to about 40% (by weight) of an emollient, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C. The immobilizing agent is a high molecular weight polyethylene glycol having the formula: $\text{H}(\text{OCH}_2\text{CH}_2)_x\text{OH}$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles.

Vega, et al. is directed to absorbent articles having a skin care composition deposited on at least a portion of the article. The skin care composition is a breathable, barrier protectant which can be immobilized on the article and is transferable to the wearer's skin via contact, normal wearer motion, and/or body heat. The skin care composition may comprise an emollient in an amount of from about 5 to about 95 wt.% of the skin care composition; an immobilizing agent in an amount of from about 5 to about 95 wt.% of the skin care composition, and optionally a humectant. Vega, et al. state that the compositions preferably fully melt at a temperature significantly above room temperature, and typically are applied to the article by heating the composition to a temperature in the range from about 35°C to about 150°C prior to application. Vega, et al. also state that the compositions preferably have a melt profile wherein 2-50% of the composition is liquid at room temperature (20°C).

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2143 requires that the Office must meet three criteria: (1) the prior art reference must teach or suggest all of the claim limitations; (2) there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference, and (3) there must be some reasonable expectation of success. An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. The common sense of those skilled in the art can demonstrate why some modifications

and/or combinations would have been obvious where others would not.¹ The Office has clearly failed to meet its burden under number (1) and/or (2) above, as the cited reference does not teach or suggest all of the claimed limitations and there is no apparent reason to modify the reference to arrive at each and every limitation of Applicants' claim 1. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Applicants respectfully submit that Vega, et al. fail to disclose a composition comprising the specific combination of an immobilizing agent that is a high molecular weight polyethylene glycol having the formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent. Nor is there any motivation in Vega, et al. to arrive at such a composition.

For instance, Applicants maintain that Vega, et al. fail to disclose a composition comprising from about **1% (by weight) to about 40% (by weight) of a compatibilizing agent** at all. The Office has cited column 26, line 5 of Vega, et al. as disclosing compatibilizing agents. As the Office has correctly noted, Vega, et al. do disclose that their compositions may comprise propylene glycol, butylene glycol, and certain low molecular weight polyethylene glycols (e.g., PEG-2, PEG-3, etc.),² which

¹ Leapfrog Enterprises, Inc. v. Fisher-Price, Inc., No. 06-1402 (Fed. Cir. May 9, 2007) See also KSR Int'l Co. v. Teleflex, Inc., et al. 550 US____, 2007 WL 1237837 at 12 (2007).

² See Vega, et al. at col. 26, lines 5-7, and col. 27, lines 48-49.

may be considered compatibilizing agents.³ Vega, et al., however, fail to teach or suggest the amounts of these agents that may be present in the compositions described therein, and in particular, fail to teach or suggest compositions comprising from about 1% (by weight) to about 40% (by weight) of these compounds or of compatibilizing agents generally.

In Response to Applicant's arguments, citing In re Aller⁴, the Office has stated that although Vega, et al. fail to mention the amounts of components such as propylene glycol, butylene glycol, and certain low molecular weight polyethylene glycols, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Specifically, "wherein the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

While Applicants agree that Vega, et al. teach optional components such as propylene glycol, butylene glycol, and certain low molecular weight polyethylene glycols, Vega, et al. fail to recognize these components as compatibilizing agents, and further, **fail to even recognize the need for any compatibilizing agents.** As noted in the specification of the present invention, the compatibility of the moisturizing and lubricating compositions of the present invention is important for the processability and stability of the compositions. In particular, paragraph 66 of the specification states:

³ See specification at p. 25, ¶67.

⁴ 220 F.2d. 454, 456; 105 USPQ 233, 235 (CCPA 1955).

Incompatible compositions require a more rigorous process to ensure that mixing is complete so as to prevent the separation of the different components in the composition. More mixing requires higher energy consumption, which leads to an increase in the cost of manufacturing the products. Further, it may be very difficult for an incompatible composition to maintain acceptable stability during the life of the product, starting with shipping, transportation, and storage prior to ultimate use by the consumer. Many incompatible ingredients may tend to slowly separate from the surface of the product to which they are applied resulting in a loss of the properties of the overall composition and a potential loss in the intended benefits.

The specification further states that certain components of the moisturizing and lubricating compositions, such as several of the immobilizing agents (e.g., high molecular weight polyethylene glycols), are incompatible with some humectants, such as glycerin.⁵ Thus, in order to ensure a high degree of compatibility, the moisturizing and lubricating compositions include from about 1% (by weight) to about 40% (by weight) compatibilizing agent. Compatibilizing agents are thus important for improving processing of the compositions, and to ensure good compatibility and a substantially homogenous composition.

While Applicants recognize that in *In re Aller*, the court generally states that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation,"

⁵ See Specification at p. 25, ¶67.

Applicants assert that the Office must first consider that the particular parameter **was recognized** as a result-effective variable before the determination of the optimum or workable ranges of the parameter might be characterized as routine experimentation; that is, Vega, et al. must recognize the need for a compatibilizing agent in their composition prior to determining the optimum or workable ranges of compatibilizing agent. MPEP §2144.05(II)(B), citing *In re Antonie*, 195 USPQ 6 (CCPA 1977). None of the above-mentioned benefits of compatibilizing agents are disclosed or even recognized by Vega, et al. In particular, Vega, et al. merely list propylene glycol, butylene glycol, and certain polyethylene glycols as suitable humectants for use in their compositions.⁶ Alternately, Vega, et al. state that propylene glycol and polyethylene glycols are suitable solvents for preservatives that may be included in the compositions.⁷ There is, however, no disclosure of using propylene glycol, butylene glycol, or low molecular weight polyethylene glycols as compatibilizing agents, or of the need for compatibilizing agents generally. Nor do Vega, et al. disclose suitable amounts of propylene glycol, butylene glycol, or low molecular weight polyethylene glycols for inclusion in their compositions. Consequently, why would one skilled in the art be motivated to determine the suitable amount of compatibilizing agent for including in the compositions of Vega, et al. when Vega, et al. fail to disclose or suggest the need for such agents, and the only disclosed uses for propylene

⁶ See Vega, et al. at col. 26, lines 3-7.

⁷ See Vega, et al. at col. 27, lines 48-49.

glycol, butylene glycol, and polyethylene glycols are as humectants and/or solvents for preservatives? While one skilled in the art may be able to optimize the amount of humectant to incorporate into the compositions of Vega, et al. based on the disclosure therein, one skilled in the art would not and could not be motivated to determine a suitable amount of compatibilizing agent for inclusion in the compositions of Vega, et al. given the lack of teaching or recognition of the benefits of doing so.⁸

Furthermore, Applicants' claim 1 requires the immobilizing agent to be a **high molecular weight polyethylene glycol having the formula $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles.**

The Office has cited to column 26, lines 6-7 of Vega, et al. as disclosing applicants' claimed immobilizing agents. However, the PEGs listed in this passage are low molecular weight PEGs that are disclosed as being useful humectants. In particular, Vega, et al. disclose PEG-2, PEG-3, PEG-30, and PEG-50. These are clearly not high molecular weight polyethylene glycol having the formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles, as required by claim 1.

⁸ In the Response to Arguments section, the Office has stated that any benefits of compatibilizing agents are inherent features of the agents. Applicants note that the lack of disclosure in Vega, et al. of the benefits of compatibilizing agents is relevant to the foreseeability of modifying the amounts of propylene glycol, butylene glycol, or low molecular weight polyethylene glycol that could optionally be included in the Vega, et al. compositions. As pointed out in the above passage, one skilled in the art would not be motivated to optimize the amounts of propylene glycol, butylene glycol, or low molecular weight polyethylene glycols that are suitable for compatibilizing, as that use is not disclosed in Vega, et al.

Specifically, at paragraph [0063] of Applicants' specification, the immobilizing agents will reduce the tendency of the emollient and humectant of the composition to migrate or flow by keeping the emollient and humectant primarily localized on the bodyfacing surface of the absorbent product. Furthermore, the immobilizing agent may provide a slight tackiness to the moisturizing and lubricating composition, which may further improve transfer of the composition to the skin or membrane of the wearer. To allow for these functions, it is preferable to use **high molecular weight** polyethylene glycols such as required in claim 1 as these compounds are solids at room temperature. As well known, the melting point of polyethylene glycol increases as the molecular weight of the compound increases. For example, the melting points of various polyethylene glycols are given as follows: diethylene glycol (PEG-2) = -10-6C (F); triethylene glycol (PEG-3) = -7C (F); PEG 400 = 4-8°C (39-46°F); PEG 600 = 20-25°C (68-77°F); PEG1500 = 44-48°C (111-118°F); PEG 4000 = 54-58°C (129-136°F); and PEG 6000 = 56-63°C (133-145°F).⁹ As such, lower molecular weight polyethylene glycols (such as PEG-2 and PEG-3 taught in Vega, et al.) have melting points ranging below room temperature, and thus, cannot be solids at room temperature such as is desired of the immobilizing agent of the claimed invention. As the components (e.g., lower weight molecular polyethylene glycols such as PEG-2 and PEG-3) taught in Vega, et al. are liquid at room temperature and they can provide a soft, lubricious type

⁹ See The Merck Index, 12th Edition, Merck & Co. Inc. and Sigma-Aldrich Handbook of Fine Chemicals, 2007-2008 at page 2023.

feel (which is desirable of a humectant for use in the composition of Vega, et al.), these components **cannot function effectively as the immobilizing agents** as required in Applicants' claim 1.

Furthermore, while some of the polyethylene glycols disclosed in Vega, et al., such as PEG-30 and PEG-50, will be solids at room temperature (i.e., their melting point is higher than room temperature), there is no teaching by Vega, et al. that these components are more preferred or that a solid component is desirable at all over any other humectant. As such, there is no reason for one skilled in the art to pick and choose between the polyethylene glycols for use as an optional humectant in the composition of Vega, et al., and specifically, to choose PEG-30 or PEG-50 over PEG-2 and PEG-3 as the humecant.

Additionally, the Office has stated that high molecular weight PEGs are disclosed in U.S. Patent No. 4,556,560 (citing column 13, lines 6-11), and that this patent is incorporated into Vega, et al. by reference on column 26, line 64, and as such, the teaching of using high molecular weight PEGs in an absorbent product should be treated as part of the Vega, et al. reference. The '560 patent referred to by the Office discloses methods for the treatment and prevention of diaper rash and diaper dermatitis using the topical application of a lipase-inhibiting agent, e.g., a water-soluble metallic salt, applied in combination with a barrier-like vehicle. The ointment compositions described in the '560 patent may comprise a mixture of short and long chain polyethylene glycols. In particular, column 13, lines 7-11 states that the high molecular weight

polyethylene glycol polymers "have an average molecular weight of about 2,000 or greater, preferably about 3,000 or greater, and, more preferably about 4,000 to about 6,000."

Applicants respectfully note that the '560 patent is cited by Vega, et al. as describing a non-limiting example of skin care agents that may be used in the compositions of Vega, et al. As noted above, the "skin care agent" in the '560 patent is the lipase-inhibiting agent, not the high molecular weight polyethylene glycols. Nowhere do Vega, et al. state that the high molecular weight polyethylene glycols disclosed in the '560 patent should or could be used in their compositions as an immobilizing agent. It is thus clear that Vega, et al. are teaching that the skin care agents of the '560 patent may be incorporated into their compositions. There is, however, no recognition or suggestion that high molecular weight PEGs should or could be used as an immobilizing agent in the compositions of Vega, et al.

Furthermore, the '560 patent is only one of a large group of patents and applications cited by Vega, et al. as disclosing suitable skin care agents. More particularly, the '560 patent is merely one patent in a list of at least thirteen different patents and applications that Vega, et al. state disclose suitable skin care agents. Applicants respectfully submit that this is not a teaching by Vega, et al. to use high molecular weight polyethylene glycols as immobilizing agents in the compositions of Vega, et al.

Additionally, applicants note that in order to arrive at applicants' claim 1, one skilled in the art must pick and choose

from a myriad of options in the Vega, et al. reference, without any guidance as to which options to choose to arrive at applicants' claim 1. At a minimum, one skilled in the art must choose, without the benefit of applicants' disclosure as a blueprint, two optional embodiments from Vega, et al. and combine these optional embodiments into a single embodiment.

Specifically one skilled in the art would have had to first decide to include propylene glycol, butylene glycol, or certain low molecular weight polyethylene glycols into the composition, all of which are listed in Vega, et al. as optional components in the compositions of Vega, et al.; specifically as suitable humectants or in the case of propylene glycol and polyethylene glycols, also as solvents for preservatives. After deciding to include one or more of these optional components, one skilled in the art would then have to determine the amount of propylene glycol, butylene glycol, or certain low molecular weight polyethylene glycols to include into the composition. However, as noted above, Vega, et al. do not disclose that any of these agents may be used as compatibilizing agents, or disclose the need for compatibilizing agents in general. Thus, the optimization of amounts for these agents must be done with no guidance by Vega, et al. as to what should be optimized.

One skilled in the art would then have to decide to select an immobilizing agent from a laundry list of thirteen patents and applications listed by Vega, et al. as disclosing optional skin care agents, with no guidance provided by Vega, et al. that suitable immobilizing agents are listed in any of those patents or applications, and then select the '560 patent from this list,

again with no guidance by Vega, et al. to select this particular patent from the laundry list of thirteen patents and applications. One skilled in the art must then incorporate a high molecular weight polyethylene glycol as disclosed in the '560 patent into the composition as an immobilizing agent. Again, all this must be done with no guidance by Vega, et al. as to the benefits of a composition comprising the specific combination of from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and an immobilizing agent that is a high molecular weight polyethylene glycol having the formula: $\text{H}(\text{OCH}_2\text{CH}_2)_x\text{OH}$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles. Applicants respectfully submit that it is simply not obvious to make such a combination based on the lack of guidance provided by the disclosure of Vega, et al.

With all due respect, it appears that the Office has used impermissible hindsight analysis and reconstruction when modifying the cited reference. What is important is that there is no guidance provided by Vega, et al. to arrive at the specific combination of from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and an immobilizing agent that is a high molecular weight polyethylene glycol having the formula: $\text{H}(\text{OCH}_2\text{CH}_2)_x\text{OH}$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles in a composition.

In light of the foregoing, Applicants respectfully submit that claim 1 is patentable over Vega, et al.

Claims 2-8, 10, 12-23 and 25-31 depend directly or indirectly from claim 1 and are thus patentable for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

Independent claim 32 is directed to an absorbent product comprising an absorbent substrate and a moisturizing and lubrication composition comprising from about 1% (by weight) to about 40% (by weight) of a silicone, from about 1% (by weight) to about 20% (by weight) of a humectant, from about 30% (by weight) to about 90% (by weight) an immobilizing agent, from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and a dispersing agent wherein no more than about 50% (by weight) of the components are liquid at room temperature and no less than about 50% of the components are solid at room temperature, and wherein at least about 85% (by weight) of the components of the moisturizing and lubricating composition form a single phase at a temperature of from about 45°C to about 80°C, and wherein the immobilizing agent is a high molecular weight polyethylene glycol having the formula: $\text{H}(\text{OCH}_2\text{CH}_2)_x\text{OH}$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles.

Claim 32 is patentable for the same reasons as set forth above for claim 1. In particular, Vega, et al. fail to disclose or provide any guidance as to a composition comprising the specific combination of from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent and an immobilizing agent that is a high molecular weight polyethylene glycol having the formula: $\text{H}(\text{OCH}_2\text{CH}_2)_x\text{OH}$, wherein x is the degree of ethoxylation

and is an average value of at least about 20 moles in a composition.

Claims 33, 35-40, 42, 44-56, and 58-61 depend directly or indirectly from claim 32 and are therefore patentable for the same reasons as set forth above for claim 32 as well as for the additional elements they require.

2. Rejections under 35 U.S.C. § 103(a) over Vega, et al. and Bowser, et al.

Reconsideration is requested of the rejection of claims 1, 24, 32, and 57 as being unpatentable over Vega, et al. (U.S. Patent No. 6,153,209) in view of Bowser, et al. (U.S. Patent No. 5,342,976).

Claim 1 and Vega, et al. are discussed above.

Bowser, et al. disclose a composition suitable for topical application to human skin. The composition comprises an active ingredient that can control skin barrier functions; particularly, the active ingredient can moisturize and treat skin surfaces that have become excessively dry, fissured, eroded, or otherwise damaged. Specifically, the active ingredient is (a) a long chain ω -hydroxy fatty acid or a carboxy-substituted derivative, (b) an hydroxy- or epoxy-derivative of an essential fatty acid, or an ester formed between (a) and (b). The composition further comprises a vehicle to enable the active ingredient to be conveyed to the skin in an appropriate dilution. One suitable vehicle is water.

In one embodiment, the compositions can be used in a liquid-impregnated fabric, such as a tissue wipe.

Claim 1 is patentable over Vega, et al. for the reasons set forth above. In particular, Vega, et al. fail to disclose a composition comprising the specific combination of an immobilizing agent that is a high molecular weight polyethylene glycol having the formula: $H(OCH_2CH_2)_xOH$, wherein x is the degree of ethoxylation and is an average value of at least about 20 moles, and from about 1% (by weight) to about 40% (by weight) of a compatibilizing agent. Bowser, et al. fail to overcome these deficiencies. In particular, Bowser, et al. fail to disclose a high molecular weight polyethylene glycol, as set forth in claim 1. The combination of Bowser, et al. and Vega, et al. thus fails to disclose or suggest all the limitations of claim 1.

Furthermore, as noted above, in establishing obviousness, the Office must show references that teach all of the claimed limitations along with some reason, either in the references themselves or in knowledge generally available to one skilled in the art, to modify and/or combine the references and arrive at the claimed subject matter. The mere fact that the references can be modified and combined to arrive at the claimed subject matter does not render the resultant combination obvious, unless the prior art also suggests the desirability of the combination. *In re Mill*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). A close reading of the cited references clearly indicates that one skilled in the art would not have been so motivated and, without Applicants' disclosure as a blueprint (which the Office had the benefit of utilizing), such a combination of the compositions of

the Vega, et al. and the Bowser, et al. references would not have been made.¹⁰

Applicants assert that there is nothing in the cited references or in the general knowledge of one ordinarily skilled in the art that would lead one skilled in the art to combine the Vega, et al. and Bowser, et al. references to arrive at Applicants' claim 1. Specifically, a close reading of the Bowser, et al. reference actually teaches away from the combination of the Vega, et al. and Bowser, et al. references.

Specifically, as noted above, it is desirable for the compositions of Vega, et al. to have a melt profile such that 2-50%, and preferably 3-25% of the components are liquid at room temperature (20°C).¹¹ Furthermore, Vega, et al. state that it is desirable for the emollient component of the compositions used therein to be substantially anhydrous. Vega, et al. define "substantially anhydrous" to mean the emollients or mixtures thereof typically have a water content of less than about 10%, preferably less than about 5%, more preferably less than about 1%, and most preferably less than about 0.5% by weight of the emollient component. Vega, et al. go on to state that the

¹⁰ M.P.E.P. §2142 further provides that in order to reach a proper determination under 35 U.S.C. §103(a), the Examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. Knowledge of Applicants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences." The tendency to resort to "hindsight" based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, as stated by the Federal Circuit, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. Grain Processing Corp. v. American-Maize-Products, Co., 840 F.2d 902, 904 (Fed. Cir. 1988).

¹¹ See Vega, et al. at col. 15, lines 14-15.

substantially anhydrous character of the emollients avoids overhydration of skin and the wicking effect of the absorbent core, which may draw emollient components toward the core, interfering with absorbency, and keeping the emollient away from the topsheet surface and the wearer's skin.¹²

In contrast, the Bowser, et al. composition can comprise from about 15% to 99.9999% by weight water and, preferably from 50% to 99.5% by weight water. As such, there is no apparent reason why one skilled in the art would combine the components of the Bowser, et al. reference, which are desirably incorporated into compositions having large amounts of water, e.g., at least 15% by weight water and, more preferably at least 50% by weight water, with the compositions of Vega, et al., which desirably limit the amount of components (such as water) that are liquid at room temperature, e.g., preferably comprise less than 50%, and more preferably 3-25% components that are liquid at room temperature. This is particularly true in view of Vega's concerns that the presence of water in the emollient component of the compositions may result in overhydration of the skin and may affect absorbency of the article. As such, there is no motivation or apparent reason to combine the cited references to arrive at each and every limitation of Applicants' claim 1. As such, claim 1 is patentable over the cited references.

Claim 24 depends from claim 1 and is thus patentable over the cited references for the same reasons as set forth above for claim 1 as well as for the additional elements it requires.

¹² See Vega, et al. at col. 18, lines 35-50.

Independent claim 32 and claim 57, which depends therefrom, are patentable over the cited references for the same reasons as set forth above for claim 1, as well as for the additional elements they require.

3. Double Patenting Rejections

Claims 1-8, 10, 12-33, 35-40, 42, and 44-61 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/659,862.

Applicants note this rejection is in fact a provisional obviousness-type double patenting rejection since U.S. Patent Application No. 10/659,862 has not yet issued as a patent. Applicants will address the merits of these rejections, as appropriate, if the listed application issues as a patent before the application at hand.

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CONCLUSION

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1-8, 10, 12-33, 35-40, 42, and 44-61 and allowance of all pending claims. The Commissioner is hereby authorized to charge any government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

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